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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,086	11/24/2003	Charles B. Chapman	100201800-1	7958

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EXAMINER

BOWERS, NATHAN ANDREW

ART UNIT	PAPER NUMBER
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1744

DATE MAILED: 11/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/722,086	CHAPMAN, CHARLES B.	
	Examiner	Art Unit	
	Nathan A. Bowers	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 15-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>042005, 112403</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35.U.S.C. 121:

- I. Claims 1-14, drawn to a disposable biochip, classified in class 435, subclass 288.5.
- II. Claims 15-35, drawn to a bio-analysis system, classified in class 422, subclass 78.

Inventions of Group II and Group I are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the housing of the combination includes a heating mechanism to induce decontamination. Accordingly, the biochip of the bio-analysis system does not require a heating means, whereas the biochip of the subcombination does require an integrated heating means.

The subcombination has separate utility because it can be used to analyze and subsequently pyrolyze biological samples without the aid of an associated bio-analysis system comprising a peripheral housing with extra chambers.

The examiner has required restriction between combination and subcombination inventions. Where applicant elects a subcombination, and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all

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the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

During a telephone conversation with Julia Dierker on 8 November 2006 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-14. Affirmation of this election must be made by applicant in replying to this Office action. Claims 15-35 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

- 1) Claims 1, 2, 4, 5, 8-11 and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by Mowry (US 7078237).

With respect to claims 1 and 8-10, Mowry discloses a method and apparatus for testing a pyrolyzing a biological substance using a disposable biochip. The biochip comprises a substrate (Figure 1:120) and a heating device (Figure 1:110) integrated with the substrate in order to form a pyrolysis stage (Figure 2:100). This is described in column 4, lines 8-30. Column 6, lines 30-47 indicate that the heating device is configured to generate heat sufficient to pyrolyze a biological substance disposed within the biochip. Column 6, lines 18-21 and column 8, lines 1-38 teach that reagents are introduced to a region of the substrate to interact with the biological substance before and during pyrolysis. Following pyrolysis, the biological substances are moved to a detector (Figure 2:230) where analysis is completed.

With respect to claims 2 and 13, Mowry discloses the method and apparatus set forth in claims 1 and 9. Since Mowry discloses that the pyrolyzer can achieve temperatures of up to 1000 degrees Celsius, it is inherent that the pyrolysis region becomes substantially free of contaminants during heating.

With respect to claim 4, Mowry discloses the apparatus set forth in claim 1. In addition, Mowry teaches that the heating device of the pyrolysis section (Figure 2:100) is electronically coupled to a bio-analysis device (Figure 2:230). In column 2, lines 36-54, Mowry states that many analysis devices and on-chip components are integrated upon the pyrolysis biochip.

With respect to claims 5 and 11, Mowry discloses the apparatus and method set forth in claims 1 and 9 wherein the heating device is disposed within the pyrolysis region. This is disclosed in column 5, lines 26-33.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

2) Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding (US 20030199081) in view of Mowry (US 7078237) and/or Doung (US 20020177135).

With respect to claims 1, 5-11 and 12, Wilding discloses a disposable biochip comprising a substrate and a region on the substrate having components configured to interact with a biological substance. More specifically, Wilding discloses a PCR chamber (Figure 1:22) within which nucleic acid samples interact with reagents required for amplification. This is described in paragraph [0040] and [0044]. Paragraphs [0014] and [0045] indicate that the temperature of the PCR chamber is regulated by microprocessor controlled resistance heaters positioned in the substrate. These resistance heaters are configured to assist the reagent components in interacting with the nucleic acid samples. According to the protocol of PCR, the heaters move the temperature of the biochip through at least one heating cycle to amplify the DNA. Wilding, however, does not state that the heating devices are configured to generate heat sufficient to pyrolyze the nucleic acid sample following normal thermalcycling procedures.

Mowry discloses the apparatus and method as previously described above. Most critically, Mowry discloses a biochip that comprises a substrate (Figure 1:120) and a heating device (Figure 1:110) integrated with the substrate in order to form a pyrolysis stage (Figure 2:100). This is described in column 4, lines 8-30. Column 6, lines 30-47 indicate that the heating device is configured to generate heat sufficient to pyrolyze a biological substance disposed within the biochip.

Doung discloses a disposable biochip capable of performing PCR and facilitating the detection of nucleic acid analytes through the use of hybridization arrays. Doung indicates that a plurality of heating means and thermocontrollers are utilized to regulate the temperature within reaction chambers during amplification and detection processes. In paragraph [0326], Doung teaches that it is known in the art to use heating means disposed upon a biochip to create extreme temperatures over a sufficient period of time sufficient to kill and destroy a biological sample.

Wilding, Mowry and Doung are analogous art because they are from the same field of endeavor regarding biochips.

At the time of the invention, it would have been obvious to utilize the heating means disclosed by Wilding to generate extreme temperatures in order to pyrolyze biological substances following normal thermalcycling procedures. Mowry indicates in column 4, lines 8-30 that resistive heating elements, similar to those disclosed by Wilding, are capable of producing temperatures sufficient to pyrolyze a variety of biochemical compounds. Doung teaches in paragraph [0326] that it is beneficial to destroy biological samples via heat treatment after analysis because many samples are dangerous and would pose health problems to operators if contacted.

With respect to claims 2 and 13, Wilding and Mowry/Doung disclose the apparatus and method set forth in claims 1 and 9 as set forth in the 35 U.S.C. 103 rejection above. Although not expressly disclosed, it can be inferred that the

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decontamination procedures taught by Mowry and Doung rid the biochip substantially free of contaminants.

With respect to claims 3 and 14, Wilding and Mowry/Doung disclose the apparatus and method set forth in claims 1 and 9 as set forth in the 35 U.S.C. 103 rejection above. Additionally, Wilding discloses in paragraph [0008] that the disclosed apparatus is intended to conduct clinical tests for paternity and genetic and infectious diseases. These tests (especially paternity testing) use biological substances obtained from a human source. Doung also discloses the use of assays that utilize biological substances from a human source.

With respect to claim 4, Wilding and Mowry/Doung disclose the apparatus set forth in claim 1 as set forth in the 35 U.S.C. 103 rejection above. Wilding additionally indicates in paragraphs [0051]-[0057] that the heating device is in communication with a variety of bio-analysis devices capable of detecting the PCR product.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan A. Bowers whose telephone number is (571) 272-8613. The examiner can normally be reached on Monday-Friday 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on (571) 272-1214. The fax phone


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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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